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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,671	12/10/2001	Otfried Kistner	V-262.00	2215

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,671	KISTNER ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-11,14-17 and 26-31* is/are pending in the application.

4a) Of the above claim(s) *26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-11,14-17 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed December 2, 2003 is acknowledged and entered. Newly submitted claim 26 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The immunogenic composition claimed is a patentably distinct invention. The method of making the immunogenic composition and the immunogenic composition itself are related as process of making and product made, but are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the immunogenic composition (virus antigen) can be made synthetically.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 26 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 1-4, 7-11, 14-17 and 27-31 are pending and examined. The objection to the specification is withdrawn in view of Applicant's amendment. The rejection of claims 1-7 and 10-13 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment and arguments. The rejection of claim 17 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 112

3. Newly added claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 recites a method that is "suitable for large scale production". The term "suitable" is unclear because the conditions for what makes the method "suitable" for large scale production are not defined.

Claim Rejections - 35 USC § 103

4. Claims 1-4, 7-11, 14-17 and 27-31 are rejected under 35 U.S.C., 103(a) as unpatentable over Dubensky Jr. *et al.* (5,789,245) in view of Yu et al (reference AM from IDS), for reasons of record. The claims as amended are drawn to a method for producing purified Ross River Virus (RRV) antigen/immunogenic compositions comprising the steps of infecting a cell culture with RRV, incubating the infected cell culture, harvesting the RRV produced, filtering through two filters and purifying the virus antigen. The first filter has a pore size of between about 0.3 and about 1.5 microns. The second filter has a pore size of between about 0.1 and about 0.5 microns. Newly added claims 27-31 are drawn to limitations of the methods the first filter is based on a positively charged matrix and the second filter is based on a hydrophilic matrix. The method further comprises treating the filtered virus with a nucleic acid degrading agent. With regard to these new claims, the types of filters used are simply optimization techniques that are well within the capabilities of one of ordinary skill. Regarding the treatment with a nucleic acid degrading agent, this limitation has already been addressed in the previous Office action.

Applicant's arguments have been carefully considered but fail to persuade withdrawal of the rejection. Applicant's substantive arguments are primarily directed to the assertion that:

- There is no motivation to combine the teachings of Yu with Dubensky because Dubensky's teachings relate primarily to recombinant viruses. Applicant argues that Dubensky's disclosure is of an entirely different technical field (recombinant vectors) than Yu (purified antigen).
    - In response, one would have been motivated to use Dubensky's large scale method to produce the antigens of Yu. The motivation comes from the need for candidate vaccine research using RRV antigens. Although Dubensky's method produces recombinant RRV vectors, the vectors are comprised of viral antigens. Therefore, one would have had a reasonable expectation of success that Dubensky's method would produce Yu's antigens. Applicant also argues that Yu is silent on virus purification and Dubensky is silent on virus inactivation, however, the rejection is based on a combination of the teachings.
- The prior art does not teach or suggest a second filter with a pore size that is less than 0.5 microns.
    - In response, the claims do not recite a second filter with a pore size that is less than 0.5 microns. The claims recite a second filter having a pore size between about 0.1 and about 0.5 microns. Dubensky teaches a second filter having a pore size of 0.65 microns. According to the claim language, the pore size of 0.65 microns falls within the range of about 0.1 and about 0.5 microns. Since the limits of the pore size range do not have specific cut-offs, one could reasonably

interpret that Dubensky's filter falls within the scope of the instant claimed pore size range.

- The reduction in contaminants in the instant invention is not primarily due to DNAse.
  - In response, regardless of what step causes reduction in contaminants (filtering or DNAse), the claimed method is obvious over the prior art because the combined teachings of Dubensky and Yu show the steps of filtering and the addition of DNAse. Whether the filtering causes the reduction, or the DNAse causes the reduction, the reduction of contaminants is being performed. The Office recognizes that the claimed method results in a surprisingly pure virus preparation. However, as claimed, the method steps do not clearly set forth the asserted novelty of the invention, which is that the 0.5 micron filter is primarily responsible for the surprisingly pure virus preparation. The nebulous range claimed as between about 0.1 and about 0.5 microns, does not contribute over the prior art.

Conclusion

2. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (571) 272-0896. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (571) 272-0902. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

James C. Housel 3/22/04

SBC

Stacy B. Chen
March 19, 2004